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10/564,458	01/12/2006	Annaliesa S. Anderson	21569YP	7338

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EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	PAPER NUMBER
1645	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,458	ANDERSON ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2008*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Sequence alignment report*.

Lack of Unity

1) Claims 8, 10, 17, 19 and 21 have been amended.

Claims 1-32 are under prosecution.

2) The instant application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 C.F.R 1.499, Applicants are required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-6, 8 and 9, drawn to a polypeptide immunogen comprising an amino acid sequence at least 90% identical to SEQ ID NO: 1 without amino acids 609-645 of SEQ ID NO: 2 and a composition comprising the same.

II. Claim 7, drawn to an immunogen consisting of an amino acid sequence at least 90% identical to SEQ ID NO: 1 linked to a moiety (inclusive of SEQ ID NO: 2).

III. Claims 10-17, 27 and 28, drawn to a nucleic acid comprising a nucleotide sequence encoding the polypeptide of invention I.

IV. Claims 18 and 29-32, drawn to a method of making a *S. aureus* polypeptide using a recombinant cell comprising the nucleic acid of invention III.

V. Claims 19-24, drawn to a method of inducing a protective immune response in a patient by administering an amount of the polypeptide of invention I.

VI. Claims 25 and 26, drawn to a method of inducing an anamnestic response comprising administering a polypeptide immunogen comprising an amino acid sequence at least 90% identical to SEQ ID NO: 1.

3) Inventions I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The special technical feature of invention I is a polypeptide immunogen comprising an amino acid sequence at least 90% identical to SEQ ID NO: 1, wherein if one or more additional polypeptide regions are present said regions do not provide a carboxyl terminus containing amino acids 609-645 of SEQ ID NO: 2 wherein the polypeptide immunogen provides protective immunity against *S. aureus*. However, such a polypeptide immunogen was already disclosed in the art at the time of the invention. For instance, CISTEM BIOTECHNOLOGIES

GMBH (WO 200259148 A2) disclosed a polypeptide comprising an amino acid sequence which is at least 99% identical to SEQ ID NO: 1 lacking amino acids 609-645 of SEQ ID NO: 2. See the attached sequence alignment report for the amino acid sequence with the accession number ABJ18927106 from WO 200259148 A2. Thus, the product of claim 1 does not define over the prior art. The special technical feature is not a unifying feature. Although the product of invention I, and the method of using the product of invention V or the method of making the product of invention IV, is a permitted combination under PCT Rule 13.2, in the instant case, since the product is already disclosed in the art, technically, the absence of special technical feature permits the separation of the method of using or making the product from the product itself. The special technical features of the subsequently claimed inventions are delineated above. The second claimed polypeptide of invention II and the third claimed nucleic acid of invention III do not share significant structural elements with the polypeptide product of invention I. A polypeptide is a single chain molecule which comprises amino acid residues. A nucleic acid molecule comprises purine and pyrimidine units. The methods of inventions IV, V and VI do not share significant method steps and parameters, products used, method objectives, and/or ultimate goals accomplished.

4) The Office has separated product and process claims based on lack of unity. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

5) In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper lack of unity between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope

with an allowed product claim will not be rejoined. See 'Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)', 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.* Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the lack of unity is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6) This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, the species lack the same or corresponding special technical features as these species do not share a significant common structural and/or functional element.

(A) Polypeptide species consisting of an amino acid sequence without amino acids 609-645 of SEQ ID NO: 2: (i) SEQ ID NO: 1 (claims 2-6); (ii) SEQ ID NO: 3 (claims 2-6); (iii) SEQ ID NO: 7 (claims 5 and 6); (iv) SEQ ID NO: 17 (claims 5 and 6); (v) SEQ ID NO: 20 (claims 5 and 6); and (vi) SEQ ID NO: 42 (claims 4-6). Claims 1, 8 and 9 are generic.

(B) Nucleotide sequence species: (a) SEQ ID NO: 30; (b) SEQ ID NO: 31; (c) SEQ ID NO: 32; (d) SEQ ID NO: 33; (e) SEQ ID NO: 34; (f) SEQ ID NO: 35; (g) SEQ ID NO: 36; (h) SEQ ID NO: 37; (i) SEQ ID NO: 38; (j) SEQ ID NO: 39; (k) SEQ ID NO: 40; (l) SEQ ID NO: 41; (m) SEQ ID NO: 46; (n) SEQ ID NO: 47; (o) SEQ ID NO: 48; (p) SEQ ID NO: 49; (q) SEQ ID NO: 50; (r) SEQ ID NO: 51; (s) SEQ ID NO: 52; and (t) SEQ ID NO: 53. See claim 15. Claims 10-14, 16 and 17 are generic.

7) Applicants are required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P § 809.02(a).

8) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

9) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

10) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shanon Foley, can be reached on (571) 272-0898.

/S. Devi/
S. Devi, Ph.D.
Primary Examiner
AU 1645

July, 2008